

dietary fiber at high levels which possess acceptable physical stability and viscosities.

Example II

The procedure set forth in Example I was used except that TIC Pretested® Ticalose® CMC 350 Powder was used in place of the CMC 15F. CMC 350 is sodium carboxymethylcellulose derived from cellulose and has a maximum viscosity of 3.1 Pa.s as a 2% wt./wt. aqueous solution measured with a Brookfield Viscometer using an RV#1 spindle. Various formulations, as in Example I were made and tested. The only acceptable products, based on the criteria set out in Example I, were as follows:

TDF 5 g/l, 40% soluble and 20% of soluble as CMC

TDF 10 g/l, 25% soluble and 20% of soluble as CMC

TDF 10 g/l, 25% soluble and 50% of soluble as CMC

TDF 15 g/l, 10% soluble and 20% of soluble as CMC

TDF 15 g/l, 10% soluble and 80% of soluble as CMC

TDF 15 g/l, 40% soluble and 80% of soluble as CMC

This Example demonstrates that the higher viscosity CMC's are also useful in the present invention, however, there are numerous products which are outside the solution space of the equation.

Example III

This control experiment used the procedure set forth in Example I except that an unhydrolyzed CMC known as TIC Pretested® Ticalose® from TIC Gums, Inc. was used in place of the CMC 15. CMC 2500 is a carboxymethylcellulose that has a viscosity of 1000–2000 Pa.s as a 2% wt/wt aqueous solution measured with a Brookfield Viscometer using an RV #1 spindle at 60 rpm. This example failed as the product gelled and was therefore impossible to process. This example demonstrates that CMC with a viscosity of greater than 3.5 Pa.s, when measured as a 2% wt. to wt. aqueous solution with a Brookfield Viscometer using a RV#1, is outside the scope of the invention.

CONCLUSION

The improved fiber containing hydrolyzed nutritional formula according to this invention possesses improved physical stability compared to formulas that do not utilize the fiber blends of this invention. This invention also provides a physically stable formula with hydrolyzed protein that is useful in the treatment of infantile colic, diarrhea, short gut syndrome and other pediatric maladies. The problems encountered by the medical and infant nutrition industry in preparing products that contain dietary fiber and which exhibit good shelf life (product stability) and acceptable viscosities are unique. Due to the high levels of minerals, vitamins and fiber found in these products, the nutritional industry, until now, has failed to provide a solution to this long felt need. Through the use of the invention described herein, the industry can prepare and supply hydrolyzed nutritional products containing physiologically effective levels of total dietary fiber that exhibit improved physical stability without unacceptable viscosities. The medical community has a continuing need for new products that will assist in the management of colic in infants and diarrhea in tube fed patients.

While the process, product and methods of this invention have been described in detail, it is to be understood that the invention is not limited to the precise examples given and that changes and variations may be made therein without departing from the scope of the invention which is defined in the following claims.

What is claimed is:

1. A low viscosity liquid nutritional formula with improved physical stability, said formula comprising:

- (a) a source of amino nitrogen selected from hydrolyzed protein, amino acids and mixtures thereof; and
- (b) a total dietary fiber blend, said fiber blend being of a concentration between 3 and 15 gms per liter of formula, wherein said fiber blend comprises soluble/non-fermentable fiber and at least one fiber selected from insoluble/non-fermentable fibers, soluble/fermental fibers and mixtures thereof; and wherein the concentration of said total dietary fiber blend in g/l is (T), the percent of total dietary fiber that is soluble can range from 10 to 40 by weight is (S) and the weight percent of soluble fiber that is said soluble/non-fermentable fiber can range from 20 to 80 is (C); and wherein the resultant to the equation:

$$8.473 - 0.39167 \times T - 0.37357 \times S + 0.08099 \times C + 0.01167 \times T \times S + 0.00139 \times C \times S - 0.00119 \times C^2 + 0.00302 \times S^2 \text{ must be equal to or less than } 3.0.$$

2. The low viscosity liquid nutritional formula according to claim 1 which additionally comprises at least one component selected from the group consisting of fat, carbohydrates, vitamins, and minerals.

3. The low viscosity liquid nutritional formula according to claim 2 wherein said source of amino nitrogen being of a concentration of between 10 and 70 gms per liter of formula; said fat being of a concentration of between 20 and 45 gms per liter of formula; and said carbohydrates, including those from dietary fiber, being of a concentration of between 60 and 190 grams per liter of formula.

4. The low viscosity liquid nutritional formula according to claim 1 wherein said source of amino nitrogen is selected from the group consisting of free amino acids, hydrolyzed soy protein, hydrolyzed caseinates, hydrolyzed whey and mixtures thereof.

5. The low viscosity liquid nutritional formula according to claim 1 wherein said fiber blend is a mixture of hydrolyzed carboxymethylcellulose and at least one fiber selected from the group consisting of oat hull fiber, gum arabic, guar gum, citrus pectin, low methoxy pectin, high methoxy pectin, barley glucans, oat glucans, pea hull fiber, soy hull fiber, soy cotyledon fiber, beet fiber and corn bran.

6. The low viscosity liquid nutritional formula according to claim 1 wherein T can range from 5 to 10 gms/l and S can range from 20 to 40.

7. The low viscosity liquid nutritional formula according to claim 6 wherein T can range from 6 to 10 g/l, S can range from 25 to 35 and C can range from 20 to 40 or 60 to 80.

8. The low viscosity liquid nutritional formula according to claim 7 wherein T is about 10 g/l, S is about 35 and C is about 20.

9. The low viscosity liquid nutritional formula according to claim 8 wherein the fiber blend is a mixture of hydrolyzed CMC, gum arabic and oat fiber.

10. The low viscosity liquid nutritional formula according to claim 9 wherein said formula contains about 2.8 g/l gum arabic, about 6.5 g/l oat fiber and about 0.7 g/l of CMC.

11. The low viscosity liquid nutritional formula according to claim 5 wherein said fiber blend is a mixture of hydrolyzed carboxymethylcellulose, oat hull fiber and gum arabic.

12. The low viscosity liquid nutritional according to claim 2 wherein the fat is selected from the group consisting of soy oil, coconut oil, fractions of coconut oil, corn oil, safflower oil, high oleic safflower oil, peanut oil, palm olein oil, olive oil, marine oil, egg yolk oil, sunflower oil, high oleic